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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,152	02/20/2004	Rafail Zubok	532/7X2	7040
51640	7590	09/19/2006	EXAMINER	
SPINE MP LERNER, DAVID, et al. 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			PELLEGRINO, BRIAN E	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/783,152

Applicant(s)

ZUBOK ET AL.

Examiner

Brian E. Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 13-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 16 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

This application contains claims directed to the following patentably distinct species:

Specie I: Figs. 7-9.

Species II: Figs. 10,11.

The species are independent or distinct because the two implant tools both operate differently and have different capabilities, for example the tool illustrated as Specie II allows for distraction of the vertebrae and the other tool allows to push the implant into the space where the prosthetic device is to be implanted.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, none are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

During a telephone conversation with Raymond Garguilo on 9/13/06 a provisional election was made without traverse to prosecute the invention of Specie II, claims 1-12,16,17. Affirmation of this election must be made by applicant in replying to this Office action. Claims 13-15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected specie. Claim 13 recites a manipulation device, which is inserted into the plying device and can be seen in Fig. 9.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Specification***

The specification is objected to because reference character "5120" has been used to designate both "prong" and "leg" in paragraphs 48,49 respectively.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3,5,9,11, 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Marnay (WO 91/13598). Fig. 10 shows an instrument having a plying device with two distal ends **811,821** with two opposing fork-shaped extensions. Fig. 11 shows the instrument has a U-shaped member with a pair of laterally spaced tines **812,813** oriented perpendicular to base (**811,821**) that terminates from elongate section **820**. It can also be seen (Fig. 11) that the fork-shaped extensions are oriented offset from the longitudinal axis of the plying device and interior sides face each other and are “adapted to” releasably grasp an intervertebral disc. It can also be construed that since the height of the base is greater than the fork-shaped extensions (Fig. 10) that the base forms a vertebral body stop. The fork-shaped extensions are fully capable of distracting an intervertebral space since the device is hinged (Fig. 10) and has at least two hinges (Fig.11). Fig. 1 shows an artificial intervertebral disc with upper and lower baseplates **110,120** with apertures to engage the fork-shaped extensions.

Claims 1-3,5,8-11,16 are rejected under 35 U.S.C. 102(b) as being anticipated by Keller (DE 3023942). Fig. 1 shows a vertebral prosthesis with upper and lower baseplates **3** that is placed in the vertebrae using a plying device having fork-shaped extensions **19** having a curved inner profile that engages the curved exterior section **1** of the prosthesis. Fig. 6 shows the plying device has at least two hinges.

Claims 1-3,5-10,16 are rejected under 35 U.S.C. 102(b) as being anticipated by Neumann (EP 1219266). Fig. 1 shows a vertebral prosthesis that can be construed to

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have upper and lower baseplates that is placed in the vertebrae and can be capable of distracting vertebrae by raising the telescoping portions of the prosthesis. Fig. 9 shows the fork-shaped extensions **27** offset from the longitudinal axis. Fig. 11 illustrates the fork-shaped extension having a base **26** and a pair of laterally spaced tines perpendicular to the base and slight notches in the interior between the upper and lower tines. Fig. 12 shows the upper portion of the base forms a forward ridge since it extends over the lower tines. Fig. 12 also shows the curved inner profile of the fork-shaped extension engaging the curved exterior section of the prosthesis.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4,17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marnay. Marnay is explained above. However, Marnay fails to disclose one of the tines aligned longitudinally with the elongate section of the instrument. Marnay does disclose a centrally located dome within the plates (Fig. 1) and teeth on the exterior of the plates apart from the dome. It would have been an obvious matter of design choice to modify the location of the tines, since applicant has not disclosed that using a tine that is longitudinally aligned with the elongate section of the fork-shaped extension or between spaced apart teeth provides any advantage, or solves a stated problem, or is used for

any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the location of tines taught by Marnay or the claimed aligned tine or centrally located tines in claim(s) 4,17 because both instruments perform the same function of holding a spinal implant and enabling a surgeon to implant the prosthesis.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marnay in view of Michelson (6080155). Marnay is explained supra. However, Marnay does not disclose the extensions are detachable. Michelson shows (Fig. 2) detachable prongs from the instrumentation. Michelson also teaches (col. 21, lines 2-4,15-19) that the detachable extensions enable the surgeon to stabilize the implant and perform any other procedures at the implantation site by not having an elongate instrument extending from the patient. It would have been obvious to one of ordinary skill in the art to utilize a detachable forked extension as taught by Michelson and modify the instrumentation of Marnay such that the tool enables the surgeon to separate the handle from the extensions and thus prevents any inadvertent movement of the implant and allows the surgeon to perform any other necessary surgical measures.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-Th (9am-6:30pm) and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700, AU 3738

**BRIAN E. PELLEGRINO**  
**PRIMARY EXAMINER**

A handwritten signature in black ink that reads "Brian E. Pellegrino". The signature is written in a cursive, flowing style with a large, stylized "B" and "P".